Dr. R. M. McCracken
Chief Veterinary Officer
Department of Agriculture for Northern Ireland
Dundonald House
Upper Newtownards Road
Belfast BT4 3SB, Northern Ireland

DEC 6

Dear Dr. McCracken:

The Food Safety and Inspection Service has completed an on-site audit of Northern Ireland's meat inspection system. The audit was conducted from May 17 through May 23, 2000. We received your letter dated October 18, 2000 with your comments and timetable for the correction of noncompliances. This correspondence has been incorporated into the final report as Attachment "G". Enclosed is a copy of the final audit report.

If you have any questions regarding the audit or need additional information, please contact Ms. Sally Stratmoen, Chief, Equivalence Branch, International Policy Division. Her telephone number is 202-720-3781 and her fax number is 202-690-4040.

Sincerely,

Sally Stratmoen

Mark Manis
Director
International Policy Division
Office of Policy, Program Evaluation
and Evaluation

Enclosure

United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR NORTHERN IRELAND
MAY 17 THROUGH 23, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Northern Ireland's meat inspection system from May 17 through 23, 2000. The establishment certified to export meat to the United States (#9014) was audited. There was no slaughter at this facility: only processing operations were conducted. Two establishments had been certified for U.S. export when this audit was planned; the management of one of these (Establishment #9056) elected to withdraw its eligibility for the United States several days prior to its scheduled audit by FSIS. The auditor was informed by the Department of Agriculture and Rural Development in Northern Ireland (DARDNI) officials that there were no plans to undertake to reinstate Est. 9056's certified status within the foreseeable future.

The last audit of the meat inspection system of Northern Ireland was conducted in February 1999. Two establishments were certified for U.S. export at that time; both were audited and were found to be acceptable. No deficiencies were reported.

Deficiencies identified during this new audit included an inadequate maintenance and cleaning program for product-contact equipment, unreliable timeliness of reporting of results and corrective actions following unsatisfactory water potability checks, and lack of pre-shipment document reviews.

Importation of beef or beef products was not allowed at the time of this audit due to the presence of Bovine Spongiform Encephalopathy (BSE) in the United Kingdom. The only restriction on pork products was that the product must be indigenous and processed in a dedicated establishment that receives no animals from countries where Swine Vesicular Disease exists (these conditions were fulfilled in Northern Ireland).

In 1999, one establishment (9014) exported 2,400 lbs. of cured pork and pork sausage to the U.S. In the first 4 months of 2000, this establishment exported 29,948 lbs. of cured pork and pork sausage to the U.S.; there were no rejections at U.S. ports of entry.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with national meat inspection officials of Northern Ireland to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by an on-site visit to the establishment. The fourth involved visits to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Northern Ireland's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Based on the performance of the single establishment, Northern Ireland's "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls In Place.

Effective inspection system controls were found to be in place in the establishment; it was recommended for re-review. Details of audit findings, including compliance with HACCP and SSOP programs are discussed later in this report.

Entrance Meeting

On May 17, an entrance meeting was held at the Belfast offices of the Department of Agriculture and Rural Development for *Northern* (DARDNI), and was attended by Dr. Robert M. McCracken, Chief Veterinary Officer (CVO); Dr. Robert Houston, Deputy CVO; Dr. Robert Huey, Divisional Veterinary Officer; Dr. Liam McNiel, Veterinary Officer; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. The audit itinerary and lodging accommodations were discussed.

2. The auditor provided the DARDNI officials with a printed copy of the latest quarterly enforcement report and informed them how to access the information via the FSIS homepage, and inquired whether Northern Ireland makes similar data available to the public; the officials replied that there was, as yet, no publication of enforcement actions by DAFRD on the internet, although there were plans to offer it in the foreseeable future. Two monthly periodical publications for the U.K., one for BSE and one for a Hygiene Assessment System (HAS), were available to the general public.

3. The auditor provided copies of the data-collection instruments that would be used during the establishment audit for SSOPs and the HACCP program.

4. The auditor gathered data to update the country profile for Northern Ireland.

Headquarters Audit

An overview of the organizational structure of Northern Ireland's inspection system was presented.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audit of the establishment be led by the inspection official that normally conducts the periodic reviews for compliance with U.S. specifications. The FSIS auditor (herein-after called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. This records review focused primarily on food safety hazards and included the following:

- Internal audit reports
- Supervisory visits to the establishment that was certified to export to the U.S.
- Training records—inspectors/lab personnel
- Enforcement actions
- Consumer complaints/Recalls
- Product seizures and similar actions
- Export certificates

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in the establishment certified by Northern Ireland as eligible to export meat products to the United States were full-time Veterinary Service employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audit

Two establishments were certified to export meat and/or poultry products to the United States at the time this audit was planned. One of these (Est. 9056) relinquished its U.S. certification several days before it was due to be audited. Government inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products in the remaining establishment (9014).

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about intra-laboratory quality assurance procedures, including sample handling, and methodology.

The Veterinary Sciences Division Laboratory in Stormont, Belfast was audited on May 22, 2000. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. Unknown intra-laboratory check samples were performed together with all routine field sample analyses, which were being run at least once per month.

Northern Ireland's microbiological testing for *Salmonella* was being performed in DARDNI's Food Microbiology / Food Science Division Laboratory, which was audited on May 22. No concerns arose as a result of this audit.

Establishment Operations

The operations conducted at Establishment 9014 were beef, pork, and lamb boning and fresh/ frozen sausage production and (not for U.S. export) pressed and sliced pork liver. As stated above, no beef was exported to the U.S. due to the presence of BSE.

SANITATION CONTROLS

Based on the on-site audit of the establishment, Northern Ireland's inspection system had controls in place for chlorination procedures; back-siphonage prevention; hand-washing facilities; sanitizers; pest control and monitoring; temperature control; lighting; opera-tional and inspectors' work space; ventliation; over-product ceilings; dry-storage areas; welfare facilities; outside premises; personal dress, habits, and hygiene practices; preven-tion of cross-contamination; equipment sanitizing; product reconditioning; operational sanitation; and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

Pre-Operational Sanitation and Product Contact Equipment

The maintenance and cleaning program for product contact equipment was found to be deficient. Many plastic edible product trays had cracked and broken edges, and were in need of repair or replacement. Two of the four large stainless combo bins had cracked and broken edges, one plastic liner was torn, providing inadequate protection of the product it contained, and grease was found on the edges of the combo bins. The conveyor belt for bones, which was positioned directly above exposed product work areas, was grossly deteriorated, with heavily frayed edges and a deeply gouged surface. This was not in itself a problem, but the stainless steel trough between it and the work area left the first foot of this conveyor belt completely exposed over the production area. Also, there were several significant gaps in this trough. Black debris was found on the majority of cutting boards and stainless steel product-contact surfaces in the production area before the start of operations. DAFRD officials took immediate corrective actions, ensuring that all affected equipment was properly cleaned and sanitized before the start of operations, and prompt repair/ replacement of deteriorated equipment was scheduled.

Water Potability Controls

A routine water sample was taken from the tap in the boiler room on Wednesday, June 29, 1999. The sample was received in the laboratory the same day and was tested the following day. The result was unsatisfactory, due to a high (>3,000) total plate count at 37ºC. The results were mailed (there was no telephone call or fax notification) on July 5, to the inspection team, which was based in an nearby slaughter facility, and were received by them a day or two later. The veterinarian immediately called the laboratory in Belfast and requested a new sample. No product was retained. The quality control person, as soon as she received (by fax) a copy of the information from the policy division of the inspection service, called the veterinarian and was told that he had taken action. Re-sampling of water from the same source, and also from the water main entering the establishment, was not done until July 22. These samples were received in the lab the same day and tested the following day. The results were satisfactory and were reported via the postal service three days later. A total of 19 days had elapsed from the laboratory's determination that the water sample was unacceptable until the inspection service received the satisfactory report.

Another routine water sample was taken from the tap in the canteen on Thursday, April 27, 2000. The sample was received in the laboratory the same day and was tested the following day. The result was unsatisfactory, due to a high (>3,000) total plate count at 22ºC. The results were mailed (there was no telephone call or fax notification) on May 1, to the inspection team, which is based in an nearby slaughter facility. This was received by them a day or two later. The veterinarian called the lab in Belfast on May 15 and requested a new sample, and called the quality assurance person to inform her and to say that he had requested a follow-up sample. No product was retained. Re-sampling was not done until May 17, of water from the same source and also in the boning room. No product had been retained. At the time of this audit, the results were still pending.

The efficiency of the reporting procedures and controls to ensure that prompt corrective actions are taken in the event of unacceptable water test results were discussed during the

country exit meeting. An improved, reliable system of reporting of results and corrective action was developed and implemented within several days of the establishment audit.

Documentation

Pre-operational sanitation activities were adequately documented, but documentation of operational sanitation activities needed improvement.

ANIMAL DISEASE CONTROLS

Northern Ireland's inspection system had controls in place to ensure adequate condemned and restricted product control and procedures for sanitary handling of returned and rework product. No slaughter establishments were certified as eligible to produce for export to the United States at the time of this audit. All pork used in U.S.-eligible product originated at Est. 332, in the Republic of Ireland. This establishment was certified to produce product for export to the United States.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

There was a system of full identification and tracking of movement of all bovines from birth to death, called the Animal and Public Health Information System (APHIS), which replaced the Animal Health Computer in 1998. This was demonstrated for the auditor. Information was also being provided to DAFRD by veterinarians at all sale barns and when doing tuberculin testing.

RESIDUE CONTROLS

Northern Ireland's National Residue Testing Plan for 2000 was being followed, and was on schedule. The inspection system of Northern Ireland had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The inspection system of Northern Ireland had controls in place to ensure adequate pre-processing trim, processed product re-inspection, identification of ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment, and post-processing handling.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic

inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, with one exception: no formal pre-shipment reviews were being performed. This requirement was explained in detail during the exit meetings in the establishment and at the headquarters offices in Belfast, and was to be implemented immediately.

ENFORCEMENT CONTROLS

Inspection System Controls

The DARDNI inspection system controls [control of restricted product and inspection samples, processed meat re-inspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible live-stock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

The processing establishment was not required to perform *Salmonella* testing (no ground meat was produced as a final product). Northern Ireland had implemented the same *Salmonella* testing program, as described in the PR/HACCP final rule, for the slaughter facility, which had voluntarily relinquished its U.S. certification.

Species Verification Testing

At the time of this audit, Northern Ireland was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

There were two internal reviewers, called Regional Veterinary Managers. Both were veterinarians with at least 5 years' experience in establishments, and similar time in headquarters policy positions. All had had special instruction and ongoing training in foreign requirements, and were being provided promptly with copies of new information by Dr. Robert Huey, Divisional Veterinary Officer, Policy.

Each establishment listed for U.S.-eligibility was being reviewed, by either one or the other of the two reviewers, once per month. Other meat establishments in Northern Ireland were also reviewed, but not monthly. None of the reviews of the U.S.-eligible establishments were announced to the establishment management, but some were announced to the inspection personnel (one day in advance).

One copy of each report generated by the internal reviewers was maintained on file in the establishment, one was retained by the internal reviewer, and one copy at headquarters. These records were being maintained on file for at least two years.

The internal reviewers were reporting their findings to Dr. Robert Huey, Divisional Veterinary Officer, Policy, who would, in case of serious noncompliance, pay a personal visit to the establishment the same or the next day. All U.S.-eligible product produced on the day of the unacceptable evaluation would be retained pending Dr. Huey's visit and evaluation. Dr. Huey had full authority up to an including withdrawal of U.S. certification.

After observing one of the internal reviewers' activities in the field, the auditor was confident in his professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Northern Ireland's internal review program as a whole.

Enforcement Activities

Northern Ireland had developed a full system of enforcement capability, which was well documented in an information packet entitled Veterinary Services Procecutions Policy, which was available to the general public. This contained summaries of official DADRNI enforcement activities and actions.

Exit Meetings

An exit meeting was conducted in Belfast on May 23. The Northern Irish participants were: Dr. Bert Houston, Deputy Chief Veterinary Officer; Dr. Colin Hart, Senior Principal Veterinary Officer; Dr. Robert Huey, Divisional Veterinary Officer; Dr. Pat Treanor, Divisional Veterinary Officer; Dr. John McEvoy, Veterinary Research Officer, Residues Laboratory; Dr. Glenn Kennedy, Senior Veterinary Research Officer II, Biochemistry; Mr. Gerry McCracken, Principal Officer; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The audit findings were discussed:

1. Several instances of inadequate cleaning of product-contact equipment prior to pre-operational sanitation inspection were observed. All affected equipment was cleaned and sanitized before operations were begun.

2. Numerous examples of deteriorated product-contact equipment, in need of repair or replacement, were found to be in use. Establishment officials agreed to implement a policy of improved maintenance and monitoring, and replacement where necessary.

3. No formal pre-shipment reviews were being conducted as required. The auditor explained the requirement in detail; DARDNI officials gave assurances that they would ensure that establishment compliance would be implemented promptly and verified regularly.

4. The system in effect did not ensure timely re-sampling of water for potablilty in the event of noncompliant water samples. An improved, more reliable system was developed and implemented within several days of the establishment audit.

5. Documentation of operational sanitation activities in the establishment was in need of improvement: establishment officials agreed to correct this immediately.

CONCLUSION

The inspection system of Northern Ireland was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments.

The controls for maintenance and cleaning of product-contact equipment prior to the start of operations in the sole establishment listed, at the time of this audit, as eligible to produce product eligible for export to the United States, were found to have been ineffective and in need of considerable improvement. The establishment was evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad
International Audit Staff Officer

(signed)Dr. Gary D. Bolstad

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Reserved for the data collection instrument for *E. coli* testing (not applicable to Northern Ireland)
D. Reserved for the data collection instrument for *Salmonella* testing (not applicable to Northern Ireland)
E. Laboratory audit forms
F. Foreign Establishment Audit Form
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
H. FSIS Response(s) to Foreign Country Comments (when it becomes available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
9014	√	√	√	√	√	√	√*	√

7* Pre-operational sanitation activities were adequately documented, but documentation of operational sanitation activities needed improvement.

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
9014	√	√	√	√	√	√	√	√	√	√	√	√

No formal pre-shipment reviews were being conducted as required. The auditor explained the requirement in detail; DARDNI officials gave assurances that they would ensure that estab-lishment compliance would be implemented promptly and verified regularly.

Attachment E-1

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
5/22/00	Veterinary Sciences Division

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Agriculture and Rural Development	Belfast, Northern Ireland	Stony Road, Stormont

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Drs. Glenn Kennedy, John McEvoy, Rob Huey

				Residue Code/Name ▶	200	500	800	907	910	923						
	REVIEW ITEMS	ITEM #														
SAMPLING PROCEDURES	Sample Handling	01	EVALUATION CODE		A	A	A	A	A	A						
	Sampling Frequency	02			A	A	A	A	A	A						
	Timely Analyses	03			A	A	A	A	A	A						
	Compositing Procedure	04			O	O	O	O	O	O						
	Interpret Comp Data	05			O	O	O	O	O	O						
	Data Reporting	06			A	A	A	A	A	A						
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE		HP-LC	GC-MS	A	GC-MS	LC-MS	HP-LC						
	Correct Tissue(s)	08			A	Ur-ine	A	Liv	L,M	L,M						
	Equipment Operation	09			A	A	A	A	A	A						
	Instrument Printouts	10			A	A	A	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE		A	A	A	2ppb	1ppb	1ppb						
	Recovery Frequency	12			A	A	A	A	A	A						
	Percent Recovery	13			A	Qual	A	85-115	92-112	85-115						
	Check Sample Frequency	14			A	A	A	A	A	A						
	All analyst w/Check Samples	15			A	A	A	A	A	A						
	Corrective Actions	16			A	A	A	A	A	A						
	International Check Samples	17			A	A	A	A	A	A						
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE		O	O	O	O	O	O						
OTHER REVIEW		19	EVAL. CODE													
		20														

SIGNATURE OF REVIEWER J D Bolstad

DATE 5/22/00

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE	NAME OF FOREIGN LABORATORY
	5/22/00	Veterinary Sciences Division

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Agriculture and Rural Development	Belfast, Northern Ireland	Stony Road, Stormont

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Drs. Glenn Kennedy, John McEvoy, Rob Huey

RESIDUE	ITEM	COMMENTS

ANALYST	DATE	DETERMINATION	RESULTS	DATE	DETERMINATION	RESULTS
1	5/8/00	Sulfadiazine	81.1%	5/5/00	Sulfadiazine	84.6%
2	5/16/00	Carbadox	94.2%	5/9/00	Carbadox	106.8%
3	5/4/00	Levamisole	101.0%	4/8/00	Carbadox	95.8%
4	4/18/00	Steroids	Negative	4/11/00	Steroids	Negative
5	5/11/00	Clenbuterol	94.4%	3/28/00	Clenbuterol	97..5%
6	5/18/00	Nicarbazine	100.2%	5/16/00	Aminooxazolidone	93.0%

NOTE: Unknown intralaboratory check samples were being run together with all routine field determinations, at least once per month.

HH.E-2

USDA United States Department of Agriculture | Food Safety And Inspection Service | Technical Service Center | Suite 300, Landmark Center 1299 Farnam Street Omaha, NE 68102

Questions for Auditing Laboratories

General

May 22, 2000

Name & location of lab: *Dept. of Agriculture and Rural Development (NI) / Food Microbiology / Food Science Division*

Private or gov't lab? *Government*

How & when was accreditation obtained? *Accredited since 1993, United Kingdom Accreditation Service*

How & how often is accreditation maintained? *Annually*

When and how is payment for analysis provided? *All government-funded*

Are results released before payment is received? *Yes*

What are the qualifications of the analyst(s) performing the individual tasks within a method? *All have graduate degrees in environmental science and specific training in microbiology relative to their duties*

What are the qualifications of the direct supervisor of the analyst(s)? *BSc in Biological Sciences with a dual biology/biochemistry major*

Methodology for HACCP *Salmonella* samples (regulatory labs)

Does this lab analyze HACCP *Salmonella* samples? *Yes*

How are HACCP *Salmonella* samples received & recorded? *They arrive in insulated, cooled containers, via courier or bus. All are logged in immediately upon arrival.*

Are HACCP *Salmonella* samples analyzed on the day of receipt? *Yes, with the exception of samples that arrive on Fridays: these are held at 2-3°C over the weekend and analyzed first thing Monday.*

What method(s) is used for HACCP *Salmonella* samples? *Impedance system (electrical conductance) using Easter and Gibson's medium, Ogden's medium, and Rappaport-Vassiliadis Enrichment Broth*

Is it a qualitative method (i.e. +/- result)? *Yes*

Are HACCP ground beef samples analyzed for *Salmonella*? *Yes*

What is the size of the ground beef test portion? *25g*

What buffer (and what volume) is used for:

Sponge samples for *Salmonella*? *BPW*

Poultry rinsates for *Salmonella*? *N/A*

Salmonella ground beef sample homogenates? *BPW*

What is the formulation of the Buffered Peptone Water you use?

Peptone	*10.0 g/l*
NaCl	*5.0 "*
Disodium phosphate	*3.5 "*
Potassium dihydrogen phosphate	*1.5 "*
pH 7.2 ± 0.2	

What analytical controls are used for *Salmonella* analyses(i.e. control cultures, etc.)? *S. java*

Are they employed for each sample set? *Yes*

How are HACCP *Salmonella* results expressed? *Coming out of the impedance, system, results are expressed as TTD (total time to detection), and the total change in conductance levels, measured in Microsiemens. Suspect samples are then subjected to traditional biochemical tests and serotyping according to the Kaufmann-White Scheme.*

How are HACCP *Salmonella* results recorded?: *In the daily log, and summarized for forwarding to DAFRD*

How and to whom are HACCP *Salmonella* results reported? *Negative results are reported to Dr. Robert Huey, Divisional Veterinary Officer, Headquarters Policy through the postal service. There have been no positives; if there were one, it would be reported via telephone and hard copy.*

Are "check" samples periodically used to test the proficiency of the lab and analysts for *Salmonella* testing? *Yes. The lab subscribes to an external quality assurance program run by* QM-Bury. *This company supplies check samples six times each year.*

1. For individual analysts or for the lab as a whole? *For the lab; the Quality Manager provides these samples to all analysts.*
2. What species/strains are used? *S. hadar, montevideo, gallinarum, chandans are examples.*
3. How many samples are analyzed and how often? *Six times per year.*
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? *Yes*
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? *20, 50, 60, 74 are actual examples.*

<u>Methodology for HACCP generic *E. coli* samples (in-plant or other private labs)</u>

Does this lab analyze HACCP generic *E. coli* samples? *No*

Att. F

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS **FOREIGN PLANT REVIEW FORM**	REVIEW DATE 5/19/2000	ESTABLISHMENT NO. AND NAME 9014 - Eurostock Meat Marketing Ltd.	CITY Newry COUNTRY Northern Ireland
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. Henry Flynn, Pat Treanor, Rob Huey	EVALUATION ☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable	

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 M	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 A
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOPs	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	83 M
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	5/19/2000	9014 - Eurostock Meat Marketing Ltd.	Newry / Northern Ireland

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Drs. Henry Flynn, Pat Treanor, Rob Huey	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

M 01 A routine water sample was taken from the tap in the boiler room on Wednesday, June 29, 1999. The sample was received in the laboratory the same day and was tested the following day. The result was unsatisfactory, due to a high (>3,000) total plate count at 37°C. The results were mailed (there was no telephone call or fax notification) on July 5, to the inspection team, which is based in an nearby slaughter facility. This was received by them a day or two later. The veterinarian immediately called the lab in Belfast and requested a new sample. No product was retained. The quality control person, as soon as she received (by fax) a copy of the information from the policy division of the inspection service, called the veterinarian and was told that he had taken action. A resampling of water from the same source, and also at the water main entering the establishment, was not done until July 22. These samples were received in the lab the same day and tested the following day. The results were satisfactory and were reported via the postal service three days later. A total of 19 days had elapsed from the laboratory's determination that the water sample was unacceptable until the inspection service received the satisfactory report.

Another routine water sample was taken from the tap in the canteen Thursday, April 27, 1999. The sample was received in the laboratory the same day and was tested the following day. The result was unsatisfactory, due to a high (>3,000) total plate count at 22°C. The results were mailed (there was no telephone call or fax notification) on May 1, to the inspection team, which is based in an nearby slaughter facility. This was received by them a day or two later. The veterinarian called the lab in Belfast on May 15 and requested a new sample, and called the quality assurance person to inform her and to say that he had requested a follow-up sample. No product was retained. A resampling was done until May 17, of water from the same source and also in the boning room. No product has been retained. At the time of this audit, the results were still pending.

The efficiency of the reporting procedures and controls to ensure that prompt corrective actions are taken in the event of unacceptable water test results were discussed during the country exit meeting.

An improved, more reliable system was developed and implemented within several days of the establishment audit.

M 18a Many plastic edible product trays had cracked and broken edges, and were in need of repair or replacement. The meat inspection officials ordered prompt repair or replacement of the deteriorated ones.

M 18b Two of the four large stainless combo bins had cracked and broken edges, one plastic liner was torn, providing inadequate protection of the product it contained, and grease was found on the edges of the combo bins. The meat inspection officials ordcered prompt repair or replacement of the deteriorated ones and improved cleaning and pre-operational monitoring procedures.

M/M 18/33 The conveyor belt for bones, which was positioned directly above exposed product work areas, was grossly deteriorated, with heavily frayed edges and a deeply gouged surface. This was not in itself a problem, but the stainless steel trough between it and the work area left the first foot of this conveyor belt completely exposed over the production area. Also, there were several significant gaps in this trough. DAFRD officials ordered prompt replacement and installation of more adequate protection for work areas.

M 19 Black debris was found on the majority of cutting boards and stainless steel product contact surfaces in the production area before the start of operations. DAFRD officials took immediate corrective action, and all the surfaces were re-cleaned and disinfected.

M 82 Pre-operational sanitation activities were adequately documented, but documentation of operational sanitation activities needed improvement.

M 83 No formal pre-shipment reviews were being performed. This requirement was explained in detail, and was to be implemented immediately.

Department of Agriculture and Rural Development

INVESTOR IN PEOPLE

VETERINARY SERVICE

18 October 2000

Dear Dr Manis

UNITED STATES FOOD SAFETY AND INSPECTION SERVICE AUDIT REPORT FOR NORTHERN IRELAND 2000

Thank you for the copy of the United States Food Safety and Inspection Service draft audit report based on the visit by Dr Bolstad to Northern Ireland during May 2000. I, my staff, laboratory personnel and the commercial companies were most impressed by Dr Bolstad's professionalism, thoroughness and fairness as an auditor. I am therefore content to accept his comments and criticisms.

Following upon Br Bolstad's visit my staff drew up a list of the non-compliances which he had outlined at his exit meeting and with the co-operation of the commercial interest have set about correcting these deficiencies. A copy of the corrective steps agreed by the commercial company are attached to this letter as an annex.

Dealing with the non-compliances in the order laid out in the report of the exit meeting:

1. The deficiencies in cleaning observed by the auditor during the pre-operational review were entirely due to the commercial company deviating from their normal cleaning system in order to prepare for the audit inspection. Perversely, in their efforts to ensure that the equipment and tables received additional cleaning they achieved the opposite result.

2. A number of damaged trays and stainless steel tanks were observed by the auditor. These have been replaced by the commercial company.

3. At the time of the audit no formal pre-shipment review was being carried out by my staff. A pre-shipment review system is now in place in both USDA exporting premises.

Dundonald House, Upper Newtownards Road, Belfast BT4 3SB
Telephone (028) 90 524669 Fax (028) 90 525012

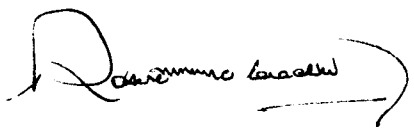
4. An improved, more reliable system for re-sampling of non-compliant water samples has been developed and implemented in the USDA/FSIS approved premises.

5. Full documentation of operational sanitation activities in both USDA/FSIS approved premises have been introduced and implemented.

If you require further information please do not hesitate to contact me.

Kind regards.

Yours sincerely



DR R M McCRACKEN
Chief Veterinary Officer

ENC

Dr Mark Manis
Director
International Policy Division
Office of Policy, Program Development and Evaluation
United States Department of Agriculture
Food Safety and Inspection Service
Washington DC 20250
United States of America.

ANNEX

TIMETABLE FOR THE CORRECTION OF NON-COMPLIANCES

Non-compliance	Agreed action	*Date for completion*
1. Bone belt in poor condition	**To be replaced**	1 November 2000
2. Stainless steel guard beneath the bone belt not continuous does not protect the table from debris.	Cutting table to be reduced in length so that the end of the belt is beyond the end of the table. Guard to be altered to achieve continuous protection.	1 September 2000
3. Room currently used as a machinery store not food standard.	To be refurbished.	February 2001
4. Blast freezer ceiling damaged and unhygienic	To be cleaned and refurbished.	1 August 2000
5. Cracked plastic over re-inspection table	To be replaced.	Completed
6. Drip from chiller in loading bay.	To be fixed	Completed
7. Damaged meat trays.	To be removed	Completed
8. Damaged metal bins	To be replaced	Completed
9. No wash-hand basin, knife steriliser adjacent to re-inspection table.	Table and lights to be moved	1 August
10. Some equipment poorly cleaned.	Cleaning SOPs to be re-examined. Schedules to be altered to indicate that some equipment should be re-washed before use, as well as immediately after use.	Completed
11. No documentation for pre-shipping review.	To be produced by QA staff in line with that contained in Generic HACCP – 3, September 1999	Completed
12. No written procedures to cover the pre-cutting check.	To be produced with statement which indicates the USDA zero tolerance policy to faecal contamination or ingesta.	Completed